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McDermott, Will & Emery

August 12, 2002

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane (Room 1061) Rockville, Maryland 20852

Re: In the Matter of Notice of Hearing: Proposal to Withdraw

Approval of New Animal Drug Application for Enrofloxacin

for Poultry ("Enrofloxacin Hearing)

FDA Docket: 00N-1571

SUBMISSION OF CONFIDENTIAL DOCUMENTS

PURSUANT TO 21 CFR § 10.20(j)(2)

Dear Sir/Madam:

As referenced in the Letter to Administrative Law Judge Davidson dated August 9, 2002, enclosed for filing please find two copies of Respondent Bayer Corporation's ("Bayer") confidential documents in response to CVM's Request for Production and Interrogatories. Bayer is submitting these documents to the confidential docket pursuant to 21 CFR § 10.20(j)(2). As a courtesy, we have also enclosed an index of these documents.

Please call with any questions.

Sincerely,

Robert B. Nicholas

Enclosures

CERTIFICATE OF SERVICE

I hereby certify that a copy of the transmittal letter for Respondent Bayer Corporation's Submission of Confidential Documents was sent via e-mail and via first-class mail, postage prepaid this 12th day of August 2002, to:

Nadine R. Steinberg, Esquire Food and Drug Administration Office of General Counsel (CGF-1) 5600 Fischers Lane, Room 7-77 Rockville, MD 20857

and was mailed, via first-class mail, postage pre-paid to:

Kent D. McClure Animal Health Institute 1325 G Street, N.W., Suite 700 Washington, D.C. 20005

and was hand delivered this 12th day of August 2002, to:

Dockets Management Branch (HFA - 305) - FDA 5630 Fishers Lane Room 1061 Rockville, Maryland 20857

Robert B. Nicholas

Bayer Corporation 00N-1571
Confidential Documents submitted Pursuant to 21 CFR § 10.20 (j)(2) Index of Documents

CONFIDENTIAL DOCKET INDEX

| Exhibit | <u>Contents</u> |
|---------|---|
| B-1155 | Reports and Studies in Response to CVM Request for Production # 1 |
| B-1156 | Documents in Response to CVM Request for Production # 4 |
| B-1157 | Documents in Response to CVM Request for Production # 9 |
| B-1158 | Documents in Response to CVM Request for Production # 16 |
| B-1159 | Documents in Response to CVM Interrogatory # 1 |
| B-1160 | Documents in Response to CVM Interrogatory # 5 |
| B-1161 | Documents in Response to CVM Interrogatory # 13 |
| B-1162 | Documents in Response to CVM Interrogatory # 16 |